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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/668,521 | 09/23/2003 | Stefan Wintersperger | 22649 | 1880 |

535 7590 09/27/2005

THE FIRM OF KARL F ROSS
5676 RIVERDALE AVENUE
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EXAMINER

MOSHER, MARY

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1648

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,521

Applicant(s)

WINTERSPERGER ET AL.

Examiner

Mary E. Mosher, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/980,029.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. PCT/EP00/04786, filed 5/25/2000. **A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e), 120, 121, or 365(c). See 37 CFR 1.78(a).** For benefit claims under 35 U.S.C. 120, 121, or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the **specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application.** If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). **This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A**

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benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(a)-(d) based upon an application filed in Denmark on 5/28/1999. A claim for priority under 35 U.S.C. 119(a)-(d) cannot be based on said application, since there is more than twelve months between the filing date and the first claimed priority date.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6682742. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the previously patented subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 00/73476. This is available as prior art solely because of the waiver of priority benefit.

Claim 1-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Antoine et al (Virology 244:365-396, 1998). Antoine teaches the full genomic sequence of MVA. The genome inherently contains many cloning sites, contains more than 200 consecutive base pairs of SEQ ID NO:1, and would hybridize under stringent conditions to SEQ ID NO:1. MVA itself is a vector, and it could be used for insertion of a heterologous sequence into its ATI region. It includes many cloning sites, transcriptional control elements, and EcoRI restriction sites. Therefore the MVA genome meets each and every limitation of these claims.

Claim 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Altenburger et al (US 5185146). Altenburger teaches MVA which comprises heterologous immunogen sequence recombined into the genome. Since the MVA genome meets the limitations of claims 1-6, the recombinant construct also meets the limitations of claims 7-9.

Claims 1-4, 6 rejected under 35 U.S.C. 102(b) as being anticipated by Shida et al (EP 261925). It is noted that the specification defines "stringent conditions" as equivalent to "homology about or above 70%." Shida teaches a nucleic acid which includes a fragment comprising at least 200 consecutive base pairs of a DNA that is at least 70% homologous to SEQ ID NO:1. See the attached alignment. Shida teaches a vector for recombining the heterologous cowpox ATI sequence in vaccinia, which inherently contains a plurality of potential cloning sites and which contains the cowpox ATI promoter. Therefore Shida meets each and every limitation of these claims.

Claims 1-11, 13, 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Paoletti 5,364,773 or WO/96/39491. Base claim 37 includes a vector which

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comprises "at least about 200 consecutive base pairs" of SEQ 1 or its complement.

Paoletti meets this limitation. As discussed in the prosecution of the parent application, applicant's SEQ ID NO:1 shares several segments of more than 200 contiguous bases which are identical to the sequence in the ATI region of vaccinia virus Copenhagen.

Therefore, as written, the claims encompass the ATI region of VV Copenhagen. If one carefully works through the construction in Example 3, it can be determined that the plasmid pSD492 contains at least nucleotides 137079-137889 and 139004-140665 of the vaccinia virus Copenhagen sequence, separated by an oligonucleotide containing multiple cloning sites. Referring to the published sequence of VV Copenhagen, nucleotides 137704- 137889 are identical to a region of SEQ ID NO:1. This is 185 contiguous base pairs, which meets the requirement for "at least about 200 consecutive base pairs". Therefore the plasmid pSD492 and subsequent constructs such as pSD493KBG and vP581, meet each and every limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shida et al (EP 261925) or Paoletti et al (US 5,364,773 or WO 96/39491) in view of Altenburger et al (US 5185146) and Antoine et al (Virology 244:365-396, 1998). Shida teaches the ATI genes of vaccinia and cowpox, and explicitly suggests using this region as a site for insertion of foreign DNA in any poxvirus, preferably orthopoxvirus, see page 3 lines 32-45 for example. Both Paoletti patents provide a working example of insertion of a foreign DNA into the ATI gene of a vaccinia strain, see Example 3, and teach the further use of this strain and this insertion locus in construction of the vector NYVAC and subsequent recombinants. These references differ from the claimed invention in that the source of the ATI sequence is conventional vaccinia or cowpox, not MVA, and in that the virus receiving the foreign sequence is conventional vaccinia or cowpox, not MVA. However, Altenburger (US 5,185,146) teaches that MVA has advantages as a vector, providing motivation to choose MVA in place of conventional vaccinia. Antoine teaches the genomic sequence of MVA, and teaches that the ATI region of MVA is very similar to that of conventional vaccinia and NYVAC, see entry 136L in Table 1, and page 388, column 2, lines 1-7. Therefore the ATI region was taught as an appropriate insertion region in vaccinia by Shida and Paoletti, and the corresponding region was taught as very similar in MVA by Antoine, and reasons to

choose MVA were taught by Altenburger. Therefore use of the ATI region in MVA for insertion of foreign DNA is seen as prima facie obvious, absent unexpected results.

Copies of the Shida and Paoletti patents are not provided with this action, because they were provided in the parent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on M-T and alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9/22/05



**MARY E. MOSHER, PH.D.
PRIMARY EXAMINER**

PN EP261925-A.
PD 30-MAR-1988.
PI Shida H, Funahashi S;
PT Gene fragment coding A-type inclusion body in pox virus -
PT used in the construction of recombinant vaccinia viruses for use
PT as vaccines
PS Claim 1; Fig 3-1 to 3-10; 24pp; English.

SQ Sequence 4641 BP; 1653 A; 780 C; 1009 G; 1199 T; 0 other;

6;

| | | | |
|----|------|---------------------------------------------------------------|------|
| Qy | 1043 | taaaccgataacgataagcgaattcatgctataagacgcatgaaggctgaacgtgaaat | 1102 |
| Db | 3798 | taaactcgatagagagaaggagagacgcatgaaggctgaacgtgatctggaacgtgaaat | 3857 |
| Qy | 1103 | cgctcgtaaaaactgcggaggtaacccatgcgaacgtgaattgaaatctgaacgtagtaa | 1162 |
| Db | 3858 | cgctcgtaaaaactgcggaggtaacccatgcgaacgtgaattggaatctgaacgtagtaa | 3917 |
| Qy | 1163 | cgtgaagagggttggaatatcaactagatgctgagaaagaaaaagttaagttctacaaaag | 1222 |
| Db | 3918 | cgtgaagagggttggaatatcaactagatgcggagaaagaaaaagttaagttctacaaaag | 3977 |
| Qy | 1223 | agaactagaacgtgatcggtatctttctagtagatatcttacctcttcttcagatccaca | 1282 |
| Db | 3978 | agaactagaacgtgatcggtatctttctagtagatatcttacctcttcttcagatccaga | 4037 |
| Qy | 1283 | tgagaaaccattaccaaattatacatttcctcgcatataaaaatgtatctccggtgacaac | 1342 |
| Db | 4038 | cgagaaaccattaccaaattatacatttcctcgcatgaa---gtagaaccggtgacgac | 4094 |
| Qy | 1343 | tgaggctacag-----gttctgtagaagtagcacctccatccacagacgttacccaacc | 1396 |
| Db | 4095 | tgaggatacagaaccaaaccctgtagaagtggtgcctccatcgctccgacgttactgaacc | 4154 |
| Qy | 1397 | gat---tagtgatgtgacaccatcggtggatgtcgaaccagaacatcccccagctttctg | 1453 |

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Db 4155 aattagtagtggtgtaacaccatcggtggatgccgaaccagaacat-ccacagctttctg 4213
Qy 1454 aatatcagacttcagtatcccaagtagcagttacacctccacaaaacctgaaactccac 1513
Db 4214 aatatcagacttcggtatctcaagtagctgttacacctccacaaaacctgaaactccac 4273
Qy 1514 agattttcgaatatcagacgt-----ccgattctatagttaacaatcc----- 1556
Db 4274 agatttccgaatatcaggattatagcgaactctattctgagtaacaataaccgaatcca 4333
Qy 1557 -----acgcccattttataattcggatctcgaatttgatgatattgatatgtatc 1606
Db 4334 aaaatgtgttttagtgaattagcttatcttgatgatcttgataaacttgatgatattgatg 4393
Qy 1607 tactaccaaactagaatattacaccagaaaagacggcttgagatcaactttatctaattgg 1666
Db 4394 agtatctactaaacaatatattatgccagaaaagacggtttgagatcaactttatctaattgg 4453
Qy 1667 ttataaaaacgaaggaggccttcggttcgaaatctaatttgacttttacgcctctggcggtt 1726
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Qy 1727 catt 1730
Db 4514 catt 4517